K010666

p. 1/2

MAY - 7 2001

510(k) Summary

1.0 Date Prepared

March 5, 2001

2.0 Submitter (Contact)

Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed
Jacksonville, FL
(904) 279-7586

3.0 Device Name

Proprietary Name:	XPS 3000 System with reciprocating adapter and suction cannulae
Common Name(s):	Electrical surgical shavers, electrical debriders, drill handpieces and cutting blades, burs, rasps, reciprocating hadpieces, and cannulae
Classification Name(s):	Suction lipoplasty system and accessories; Surgical instrument, AC powered motors, accessories and attachments

4.0 Device Classification

Classification Name:	Suction lipoplasty system
Procode 79MFF	Class II 21 CFR § 878.5040
Classification Name:	Suction lipoplasty accessories
Procode 79MUU	Class II 21 CFR § 878.5040
Classification Name:	Surgical instrument, AC powered motors, accessories and attachments
Procode 79GEY	Class I 21 CFR § 878.4820

5.0 Device Description

The XPS 3000 system consists of a power control console, footswitches, connection cables, and assorted handpieces to drive various burs, blades, drills, rasps, and reciprocating cannulae.

p. 2/2

K010666

6.0 Indications for Use

The XPS 3000 with reciprocating adapter and suction cannlua is intended for the removal of soft tissue and fluid during general surgical procedures including suction lipoplasty for aesthetic body contouring.

7.0 Substantial Equivalence

The proposed XPS 3000 system is substantially equivalent in operating principle, technology, overall design, function, materials, and intended use to the XPS / Powersculpt System as decribed in K992855.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2001

Mr. Martin Sargent
Regulatory Affairs Manager
Medtronic Xomed
6743 Southpoint Drive North
Jacksonville, Florida 32216

Re: K010666
Trade/Device Name: XPS 3000 System
Regulation Number: 878.5040
Regulatory Class: II
Product Code: MUU
Dated: March 5, 2001
Received: March 6, 2001

Dear Mr. Sargent:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010666
Device Name: XPS 3000 System
Indications for Use:

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(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010666

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)